Rhode Island Department of Health
Institutional Review Board (IRB)
Minutes of Meeting
January 6, 2005

In attendance: John Fulton, Leonard Green (Vice-Chair), Ewa King (Alternate), Sharon Marable (Alternate), Bruce McIntyre, Elizabeth Shelov.

Absent but excused: Uptala Bandy, Jay Buechner, Joann Lindenmayer (Chair), Vivian Weisman.

The Vice-Chair began the meeting at 9:30 AM.

The Vice-Chair presented an overview of the project entitled: Cohort Cancer Registry Follow-Up Study (IRB Application no. 2004-10). The charge of the Board relative to this proposal was to consider the request for a waiver of informed consent. After a brief overview of the project and a more in-depth review of section 16 of the RIDOH, IRB, Application for Review, the Board on motion of Elizabeth Shelov and seconded by Bruce McIntyre, unanimously voted to accept the request for waiver of informed consent for this proposal.

Elizabeth Shelov, the primary reviewer for IRB Application no. 2004-05 The Development of Causal Learning, presented the results of her review. She stated that Dr. Sobel, the principal Investigator, was responsive to all of the issues addressed in the October 12, 2004, letter from Joann M. Lindenmayer, DVM, MPH, Chair of the RIDOH, IRB. However, Elizabeth Shelov did express some concern that the "script", proposed by Dr. Sobel, to be used when initial contact is made with potential participants, was less straightforward than desirable. Secondly, the section of the informed consent that addressed options for the use of the videotapes needs to be presented more clearly to distinguish between options. Specifically, one option gives the researchers permission to use the tapes at professional meetings and in educational settings and the other option precludes this type of use.

John Fulton stated that the Board may have been a bit too demanding requiring the investigator to cover all of the possible financial implications of participation in the study. The Board members agreed and asked that the response to Dr. Sobel indicate that he need not inform participants in such detail.

On motion of Bruce McIntyre and seconded by John Fulton it was unanimously voted that Dr. Sobel's proposal be approved with the inclusion of "script" language that will provided to Dr. Sobel by the Board. Leonard Green will circulate draft language to the Board members prior to distribution to Dr. Sobel.

A discussion was held regarding the issue of Departmental support for the IRB. Leonard Green reported that there was a plan crafted by the Department to provide personnel support to the Board. Unfortunately, at the very last moment the plan did not materialize. Sharon Marable and John Fulton expressed concern that there should be additional and more formalized efforts put forth by the Department to identify the necessary support. Leonard Green will ask that the IRB support issue be put on the Executive Committee agenda.

Mr. Green informed the members that the Chair is still pursuing various avenues for new Board members. There are a couple of individuals that are currently being contacted. Additional discussion will transpire when more concrete information is available.

Ewa King stated that her efforts to organize a discussion about informed consent between and amongst the Laboratories cooperating in the multi-state Mercury, Lead, and Cadmium Levels in Umbilical Cord Blood Pilot Study has been less than successful. She asked that the Chair of the Board contact other board chairs in the study states to organize such an effort.

The Board adjourned at 10:35 a.m.